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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/851,882	05/09/2001	Dipak Ghosh	210556	4321

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EXAMINER

YU, GINA C

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 11/25/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/851,882

Applicant(s)

GHOSH ET AL.

Examiner

Gina C. Yu

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-45 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of Amendment filed on June 17, 2003. Claims 1-45 are pending. Claim rejections as indicated in the previous Office action dated March 12, 2003 are withdrawn in view of applicants' remarks. New rejections are made in view of further consideration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "polyether derivatives" in claim 20 renders the claim vague and indefinite. It is not clear whether the "derivatives" mean ethers derived by using different types of hydrocarbons, or polyethers substituted with non-hydrocarbon atoms such as a halogen. Applicants provide no examples or explanation to indicate the meaning of the term.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

1. Claims 1-13, 17-29, and 32-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hoppe et al. (US 5889062) in view of Raab (Uses of Urea in Cosmetology, 1990).

Hoppe teaches composition comprising ubiquinones for treating senile xerosis, of which the symptoms include dryness, cracking, roughness skin by providing moisture to the skin. See col. 1, line 9 – col. 2, line 37. The reference teaches preferably using 0.2-0.4 by weight of coenzyme Q10. See col. 3, lines 4 – 15. The composition is formulated in W/O or O/W emulsion gel, lotion, or cream. See col. 3, lines 16 – 20; col. 4, lines 53- 60. The additives including emulsifiers, preservatives, buffer substances, thickeners, fragrances, antioxidants, vitamins, and UV protection filters are also to be added in the composition. See col. 3, line 21 – col. 4, line 48. See Examples III-V for the amount. The reference teaches using 0.1-10 wt % of the UV protection filters. See col. 4, lines 36 – 46.

Hoppe fails to teach adding urea.

Raab teaches the use of urea in concentrations of 4-10 wt % in cosmetic and/or dermatological compositions. See p. 97, col. 2 – p. 98, col. 1. The pharmacological activity of urea, including moisturizing, desquamating antimicrobial, and anti-inflammatory action, are disclosed on p. 98, and its moisturizing effect is discussed throughout the article. The reference teaches urea increases the therapeutic activity of other pharmaceutical substances, and in Table 3 shows the use of urea in combination with anti-inflammatory agents (glucocorticoids), tretinoin or others in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27. The reference recommends formulating urea-containing compositions in the form of emulsion lotion or cream, meeting instant claims 2, 3, and 38. See p. 102, col. 2.

It is generally considered prima facie obvious to combine two compounds each of which is taught by the prior art to be useful for the same purpose, in order to form a composition which is to be used for the very same purpose. The idea for combining them flows logically from their

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having been used individually in the prior art. See In re Kerkhoven, 626 F.2d 848, 205 USPQ 1069 (CCPA 1980). As shown by the recited teachings, the instant claims define nothing more than the concomitant use of two skin care actives conventionally used for dry skin treatment. It would follow that the recited claims define prima facie obvious subject matter.

It would have been further obvious to one having ordinary skill in the art at the time the invention was made to have modified the Hoppe invention by adding urea as motivated by Raab because of an expectation of successfully producing a topical composition for treating skin disorders including senile xerosis, with enhanced moisturizing property and improved pharmaceutical effects of other skin care actives.

2. Claims 1-12, 14, 15, 17, 19, 20, 21, 23, 24, 29, 30, 34, 35, 38, 39, 40, 41, and 43-45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin Q10 Anti-Wrinkle product package and English translation of Eucerin press release (Eucerin Pressemitteilungen, Oct. 2000) in view of Business Wire (Feb. 1, 1999), Bertelli (US 4654373) and FDC Reports (October 26, 1992).

Eucerin product packages indicates that the composition comprises water, coenzyme Q10, glycerin (moisturizer), hydrogenated coco-glycerides (solid emollient), caprylic/capric triglyceride (oil), biosaccharide gum-1 (thickener), carbomer (thickener), parabens (preservatives), titanium dioxide (sunscreen), and sodium hydroxide (base neutralizer), and tocopheryl acetate (vitamin E, an antioxidant). See instant claims 1-12, 14, 15, 17, 19, 20, 21, 23-27, 29, 30, 34, 35, 38, 39, 40, and 41.

Eucerin press release teaches that the product has been available in the market since October 2000 by Beiersdorf.

Eucerin product package and press release fail to disclose the amount of coenzyme Q10 nor teach adding urea in the composition.

Business Wire teaches that it is well known in the art that Beiersdorf uses Q-pharma's coenzyme Q10 platform technology, which is described in Bertelli (US 4654373), in topical use non-prescription products. See Full Text.

Bertelli teaches the method of formulating and topically applying pharmaceutical or cosmethological pastes, creams, ointments, gels, lotions, or unguents which comprises 0.1-10 % Coenzyme Q10 to treat damaged and impaired skin tissue. See col. 2, lines 28 – 64.

While the Bertelli reference further suggests adding other topical actives in the composition, see col. 2, lines 61 – 64, the combined references above fail to teach adding urea in the Eucerin composition.

FDC Reports teaches that Beiersdorf produces a dry skin treatment composition comprising 5 % of urea under the tradename Eucerin Plus. See p. 14, 1st par. – 4th par. The reference teaches that the product “induces significant improvements in skin dryness and appearance relative to an untreated control”. See Id.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the Eucerin anti-wrinkle treatment composition by adding 5 % of urea as motivated by Bertelli and FDC Reports, because of an expectation of successfully producing an enhanced skin treatment composition which moisturizes and treats damaged and impaired skin. The motivation to use coenzyme Q10 in the weight amount of 0.1-10 % by

weight of the total composition is found in the combined teachings of Beiersdorf press release, Business Wire, and Bertelli. The claimed methods in claims 43-45 are viewed obvious uses of the prior art cosmetic compositions.

3. Claims 13, 16, 18, 22, 28, 31, 32, 33, 36, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, and FDC Reports as applied to claims 1-12, 14, 15, 17, 19, 20, 21, 26, 27, 29, 30, 34, 35, 38, 39, 40, 41, and 43-45 as above, and further in view of Hoppe.

The combined references fail to teach the amount of the additives and auxiliary ingredients.

Hoppe, discussed above, teaches emulsion formulations comprising coenzyme Q10 and additives.

Given the teaching the additives and auxiliary ingredients used in the Eucerin formulations as shown in the combined references, it would have been obvious to one having ordinary skill in the art at the time the invention was made to have looked to the prior art such as Hoppe for the amounts of these additives in topical formulations. Furthermore, differences in concentration generally will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. See MPEP § 2144.05. Since the general conditions of the instant claims are disclosed in the combined references, examiner views that one having ordinary skill in the art would have discovered the optimum or workable ranges by routine experimentation to formulate a topically applicable, stable composition.

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4. Claims 23-25 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eucerin product package, Eucerin press release, Business Wire, Bertelli, FDC Reports, and Hoppe as applied to claims 1-22, 26-36, 38-45 as above, and further in view of Raab.

While Eucerin product package teaches that the composition is designed for sensitive skin crème, the combined references above fail to teach adding soothing agents.

Raab, discussed above, teaches urea formulations comprising anti-inflammatory agents (glucocorticoids) in the weight ratio of 10: 0.3 to 10: 5. See p. 101, first column; see instant claims 25-27.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the composition of the combined references by adding soothing agents such as glucocorticoids as motivated by Raab because of an expectation of successfully producing a topical composition effective to treat irritated skin.

Response to Arguments

Applicant's arguments with respect to claims 1-45 have been considered but are moot in view of the new ground(s) of rejection.

Applicants' data in specification has been fully considered, but examiner finds that the data does not amount to the clear and convincing evidence that overcomes the proposed obviousness of the combined teachings of the references in this case. Applicants present subjective evaluations from panelists to show that the combination of coenzyme Q10 and urea as claimed produces higher visual, after-feel, moisturizing properties. Examiner respectfully notes that the prior arts teach that urea and Coenzyme Q10 are each known as treating skin conditions such as dry and damaged skin, as shown in Bertelli, Raab, Hoppe and FDC Reports. To

overcome obviousness rejection, applicants must show that the combination of the teachings produces greater than expected results by clear and convincing evidence that is commensurate with the scope of the claims. See MPEP § 716.02. Examiner takes the position that no such evidence is shown in this case. For example, example 10 in applicants' specification demonstrates subjective evaluation of comparison among composition 10 A, which comprises coenzyme Q10 only, 10B comprising urea only, and 10C comprising urea and coenzyme Q10. While the average evaluation results are indicated as 7.2, 7, and 7.3 for tests 10A, 10B, and 10C, respectively, examiner finds that these subjective evaluation result are short of *clear and convincing* evidence to show surprising or greater than expected from combining two actives that are each said to useful for dry skin treatment. Furthermore, it is not clear what the weight amount of each component is, and thus whether the data is within the scope of the claims cannot be determined. It is also noted that the data in example 3 does not seem to correspond to the "cumulative skin moisturizing property" as shown in Table 3, which indicates that there should be more significant increase of moisture level in the composition having coenzyme Q10 and Urea combined in the ratio of 1:10. Examiner further notes that Raab teaches that urea enhances the therapeutic effects of the skin care actives. In view of the collective teachings of the reference, examiner views that the enhanced moisturizing effect as shown in Table 3 would not be an unexpected result.

Conclusion

No claims are allowed.


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gina C. Yu whose telephone number is 703-308-3951.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 703-305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Gina C. Yu
Patent Examiner


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

11/24/03